

AMENDED IN SENATE AUGUST 6, 2014

AMENDED IN SENATE JUNE 17, 2014

AMENDED IN ASSEMBLY MAY 5, 2014

AMENDED IN ASSEMBLY APRIL 23, 2014

AMENDED IN ASSEMBLY MARCH 18, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 2605

Introduced by Assembly Member Bonilla

February 21, 2014

An act to amend Sections 208, 4040.5, 4043, 4060, 4081, 4101, 4105, 4120, ~~4126~~, 4149, 4160, 4161, 4162, 4162.5, 4164, 4165, 4166, 4167, 4168, 4169, 4201, 4305.5, 4312, 4331, and 4400 of, to amend the heading of Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of, to add Sections ~~4025.5~~, ~~4022.7~~, 4044.5, 4053.1, ~~and 4107~~ ~~4107~~, and ~~4161.5~~ to, and to repeal and add Section 4045 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2605, as amended, Bonilla. Pharmacy: third-party logistics providers.

(1) Under the Pharmacy Law, a violation of which is a crime, the California State Board of Pharmacy licenses and regulates the practice of pharmacy. Existing law restricts the purchase, trade, sale, or transfer of dangerous drugs or dangerous devices, as defined, to licensed wholesalers and other authorized persons. Under the Pharmacy Law, the board licenses and regulates entities, including third-party logistics

providers, as wholesalers. The Pharmacy Law defines a “third-party logistics provider” or a “reverse third-party logistics provider” as an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. Existing law requires a wholesaler to *have a pharmacist or designated representative on its premises and to be supervised or managed by a designated representative-in-charge and representative-in-charge*. Existing law requires a separate license for each place of business owned or operated by a wholesaler. Existing law also requires a wholesaler to submit a surety bond of \$100,000 payable to a specified fund of the board to secure payment of any administrative fine imposed by the board. Existing law, the federal Drug Supply Chain Security Act, prohibits a third-party logistics provider, as defined, from conducting any activities in a state unless each facility of the provider is licensed by the state from which drugs are distributed by the provider in accordance with regulations to be promulgated by the Secretary of the United States Department of Health and Human Services.

This bill would revise the definition of the terms “third-party logistics provider” and “reverse third-party logistics provider” to conform to federal law, as specified, and would require a third-party logistics provider of a dangerous drug or dangerous device to be separately licensed by the board as a third-party logistics provider. The bill would require a third-party logistics provider to be supervised and managed by a ~~facility manager-in-charge~~ *responsible manager* who would *need to be licensed by the board as a designated representative-3PL*. Under the bill, a designated representative-3PL and a responsible manager would be subject to similar requirements as those imposed on a designated representative and a designated ~~representative-in-charge~~ *with respect to wholesalers, representative-in-charge, respectively*. The bill would limit a place of business to a single board-issued license, *except for entities under common ownership that meet specified requirements*, and would require that at least one designated representative, in the case of a wholesaler, or ~~facility manager~~, *designated representative-3PL*, in the case of a third-party logistics provider, be present during business hours for each licensed place of business. The bill would require a third-party logistics provider to submit a surety bond of \$90,000 payable to a specified fund of the board to secure payment of any administrative fine imposed by the board. *The*

bill would enact parallel requirements with respect to nonresident third-party logistics providers and would make related conforming changes and delete obsolete provisions. After specified federal regulations under the federal Drug Supply Chain Security Act are promulgated, the bill would require the board to act to identify any California laws governing interstate commerce in conflict with those regulations and act to remove the conflict.

~~The bill would~~

Existing law makes a wholesaler that uses the services of a carrier liable for the security and integrity of any dangerous drug or devices through that carrier until the drugs or devices are delivered to the transferee.

This bill would extend that liability when the wholesaler uses the services of a third-party logistics provider and would require a third-party logistics provider that uses the services of a carrier to have in place and comply with specified written policies and procedures.

(2) Existing law requires that all records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices be open to inspection by authorized officers of the law during business hours and be preserved for at least 3 years.

This bill would make those requirements also applicable to records of receipt and shipment of dangerous drugs and dangerous devices. The bill would also require a manufacturer, wholesaler, third-party logistics provider, or pharmacy that has reasonable cause to believe that a dangerous drug or device that is or was in its possession, and has been sold or distributed in or through California, is counterfeit or the subject of a fraudulent transaction to notify the board within 72 hours of obtaining that knowledge.

~~(2) The Pharmacy Law requires a person located outside this state that ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state, or sells, brokers, or distributes dangerous drugs or devices within this state to be a licensed nonresident wholesaler.~~

~~This bill would, in addition, require a person located outside this state that performs those actions or that warehouses or distributes dangerous drugs or dangerous devices into this state, or warehouses dangerous drugs or devices within this state to be licensed as either a nonresident wholesaler or a nonresident third-party logistics provider. The bill would make conforming changes, and would delete obsolete cross-references and provisions.~~

(3) Existing law sets the fees for the issuance and renewal of licenses for wholesalers and designated representatives at specified amounts and authorizes those fees to be increased to specified higher amounts.

This bill would instead set the fees at the higher amounts.

(4) Because a violation of the requirements described in paragraphs (1) and (2) above would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 ~~SECTION 1. Section 4025.5 is added to the Business and~~
2 ~~Professions Code, to read:~~

3 ~~4025.5. (a) "Facility manager" means an individual licensed~~
4 ~~by the board who oversees the operations of a third-party logistics~~
5 ~~provider with respect to dangerous drugs and dangerous devices~~
6 ~~received by, stored in, or shipped from the licensed place of~~
7 ~~business of the third-party logistics provider.~~

8 ~~(b) "Facility manager-in-charge" means a facility manager~~
9 ~~licensed by the board who is designated by a third-party logistics~~
10 ~~provider and approved by the board pursuant to Section 4160 to~~
11 ~~oversee a licensed place of business of the third-party logistics~~
12 ~~provider. The facility manager-in-charge is responsible for ensuring~~
13 ~~the compliance of the licensed place of business with state and~~
14 ~~federal laws and with the third-party logistics provider's customer~~
15 ~~specifications.~~

16 ~~SECTION 1. Section 208 of the Business and Professions Code~~
17 ~~is amended to read:~~

18 ~~208. (a) Beginning April 1, 2014, a CURES fee of six dollars~~
19 ~~(\$6) shall be assessed annually on each of the licensees specified~~
20 ~~in subdivision (b) to pay the reasonable costs associated with~~
21 ~~operating and maintaining CURES for the purpose of regulating~~
22 ~~those licensees. The fee assessed pursuant to this subdivision shall~~
23 ~~be billed and collected by the regulating agency of each licensee~~

1 at the time of the licensee's license renewal. If the reasonable
2 regulatory cost of operating and maintaining CURES is less than
3 six dollars (\$6) per licensee, the Department of Consumer Affairs
4 may, by regulation, reduce the fee established by this section to
5 the reasonable regulatory cost.

6 (b) (1) Licensees authorized pursuant to Section 11150 of the
7 Health and Safety Code to prescribe, order, administer, furnish,
8 or dispense Schedule II, Schedule III, or Schedule IV controlled
9 substances or pharmacists licensed pursuant to Chapter 9
10 (commencing with Section 4000) of Division 2.

11 (2) ~~Wholesalers and Wholesalers, third-party logistics providers,~~
12 ~~nonresident wholesalers, and nonresident third-party logistics~~
13 ~~providers~~ of dangerous drugs licensed pursuant to Article 11
14 (commencing with Section 4160) of Chapter 9 of Division 2.

15 (3) Nongovernmental clinics licensed pursuant to Article 13
16 (commencing with Section 4180) and Article 14 (commencing
17 with Section 4190) of Chapter 9 of Division 2.

18 (4) Nongovernmental pharmacies licensed pursuant to Article
19 7 (commencing with Section 4110) of Chapter 9 of Division 2.

20 (c) The funds collected pursuant to subdivision (a) shall be
21 deposited in the CURES Fund, which is hereby created within the
22 State Treasury. Moneys in the CURES Fund shall, upon
23 appropriation by the Legislature, be available to the Department
24 of Consumer Affairs to reimburse the Department of Justice for
25 costs to operate and maintain CURES for the purposes of regulating
26 the licensees specified in subdivision (b).

27 (d) The Department of Consumer Affairs shall contract with
28 the Department of Justice on behalf of the Medical Board of
29 California, the Dental Board of California, the California State
30 Board of Pharmacy, the Veterinary Medical Board, the Board of
31 Registered Nursing, the Physician Assistant Board of the Medical
32 Board of California, the Osteopathic Medical Board of California,
33 the Naturopathic Medicine Committee of the Osteopathic Medical
34 Board, the State Board of Optometry, and the California Board of
35 Podiatric Medicine to operate and maintain CURES for the
36 purposes of regulating the licensees specified in subdivision (b).

37 *SEC. 2. Section 4022.7 is added to the Business and Professions*
38 *Code, to read:*

1 4022.7. (a) *“Designated representative-3PL” means an*
2 *individual to whom a license has been granted pursuant to Section*
3 *4053.1.*

4 (b) *“Responsible manager” means a designated*
5 *representative-3PL selected by a third-party logistics provider*
6 *and approved by the board as responsible for ensuring compliance*
7 *of the licensed place of business with state and federal laws with*
8 *respect to dangerous drugs and dangerous devices received by,*
9 *stored in, or shipped from the licensed place of business of the*
10 *third-party logistics provider.*

11 ~~SEC. 2.~~

12 SEC. 3. Section 4040.5 of the Business and Professions Code
13 is amended to read:

14 4040.5. “Reverse distributor” means every person who acts as
15 an agent for pharmacies, drug wholesalers, third-party logistics
16 providers, manufacturers, and other entities by receiving,
17 inventorying, warehousing, and managing the disposition of
18 outdated or nonsaleable dangerous drugs.

19 ~~SEC. 3.~~

20 SEC. 4. Section 4043 of the Business and Professions Code is
21 amended to read:

22 4043. “Wholesaler” means and includes a person who acts as
23 a wholesale merchant, broker, jobber, customs broker, reverse
24 distributor, agent, or a nonresident wholesaler, who sells for resale,
25 or negotiates for distribution, or takes possession of, any drug or
26 device included in Section 4022. Unless otherwise authorized by
27 law, a wholesaler may not store, warehouse, or authorize the
28 storage or warehousing of drugs with any person or at any location
29 not licensed by the board.

30 ~~SEC. 4.~~

31 SEC. 5. Section 4044.5 is added to the Business and Professions
32 Code, to read:

33 4044.5. “Reverse third-party logistics provider” means an entity
34 that processes or manages the disposition of an outdated or
35 nonsaleable dangerous drug or dangerous device on behalf of a
36 manufacturer, wholesaler, or dispenser of the dangerous drug or
37 dangerous device, but does not take ownership of the dangerous
38 drug or dangerous device nor have the responsibility to direct its
39 sale or disposition. Unless otherwise specified in this chapter,

every provision of this chapter that applies to a third-party logistics provider shall also apply to a reverse third-party logistics provider.

~~SEC. 5.~~

~~SEC. 6.~~ Section 4045 of the Business and Professions Code is repealed.

~~SEC. 6.~~

~~SEC. 7.~~ Section 4045 is added to the Business and Professions Code, to read:

4045. “Third-party logistics provider” means an entity that provides or coordinates warehousing or other logistics services for a dangerous drug or dangerous device in intrastate or interstate commerce on behalf of a manufacturer, wholesaler, or dispenser of the dangerous drug or dangerous device, but does not take ownership of the dangerous drug or dangerous device, nor have responsibility to direct its sale or disposition.

~~SEC. 7.~~

~~SEC. 8.~~ Section 4053.1 is added to the Business and Professions Code, to read:

4053.1. (a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a ~~facility manager~~ *designated representative-3PL* to provide sufficient and qualified supervision of a third-party logistics provider’s place of business. The ~~facility manager~~ *designated representative-3PL* shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider’s place of business.

(b) An individual who is at least 18 years of age may apply for a ~~facility manager~~ *designated representative-3PL* license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.

(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of quality control systems.

(iv) Knowledge and understanding of the United States Pharmacopoeia *or* federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs *and dangerous devices*.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a ~~facility manager~~ *designated representative-3PL* until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A third-party logistics provider shall not operate without at least one ~~facility manager~~ *designated representative-3PL* present at each of its licensed places of business as required under Section 4160.

~~SEC. 8:~~

SEC. 9. Section 4060 of the Business and Professions Code is amended to read:

4060. A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian,

1 naturopathic doctor, certified nurse-midwife, nurse practitioner,
2 or physician assistant, if in stock in containers correctly labeled
3 with the name and address of the supplier or producer.

4 This section does not authorize a certified nurse-midwife, a nurse
5 practitioner, a physician assistant, or a naturopathic doctor, to order
6 his or her own stock of dangerous drugs and devices.

7 ~~SEC. 9.~~

8 *SEC. 10.* Section 4081 of the Business and Professions Code
9 is amended to read:

10 4081. (a) All records of manufacture and of sale, acquisition,
11 *receipt, shipment*, or disposition of dangerous drugs or dangerous
12 devices shall be at all times during business hours open to
13 inspection by authorized officers of the law, and shall be preserved
14 for at least three years from the date of making. A current inventory
15 shall be kept by every manufacturer, wholesaler, third-party
16 logistics provider, pharmacy, veterinary food-animal drug retailer,
17 physician, dentist, podiatrist, veterinarian, laboratory, clinic,
18 hospital, institution, or establishment holding a currently valid and
19 unrevoked certificate, license, permit, registration, or exemption
20 under Division 2 (commencing with Section 1200) of the Health
21 and Safety Code or under Part 4 (commencing with Section 16000)
22 of Division 9 of the Welfare and Institutions Code who maintains
23 a stock of dangerous drugs or dangerous devices.

24 (b) The owner, officer, and partner of a pharmacy, wholesaler,
25 third-party logistics provider, or veterinary food-animal drug
26 retailer shall be jointly responsible, with the pharmacist-in-charge,
27 ~~facility manager-in-charge~~, *responsible manager*, or designated
28 representative-in-charge, for maintaining the records and inventory
29 described in this section.

30 (c) The pharmacist-in-charge, ~~facility manager-in-charge~~,
31 *responsible manager*, or designated representative-in-charge shall
32 not be criminally responsible for acts of the owner, officer, partner,
33 or employee that violate this section and of which the
34 pharmacist-in-charge, ~~facility manager-in-charge~~, *responsible*
35 *manager*, or designated representative-in-charge had no knowledge,
36 or in which he or she did not knowingly participate.

37 ~~SEC. 10.~~

38 *SEC. 11.* Section 4101 of the Business and Professions Code
39 is amended to read:

1 4101. (a) A pharmacist may take charge of and act as the
2 pharmacist-in-charge of a pharmacy upon application by the
3 pharmacy and approval by the board. A pharmacist-in-charge who
4 ceases to act as the pharmacist-in-charge of the pharmacy shall
5 notify the board in writing within 30 days of the date of that change
6 in status.

7 (b) A designated representative or a pharmacist may take charge
8 of, and act as, the designated representative-in-charge of a
9 wholesaler or veterinary food-animal drug retailer upon application
10 by the wholesaler or veterinary food-animal drug retailer and
11 approval by the board. A designated representative-in-charge who
12 ceases to act as the designated representative-in-charge at that
13 entity shall notify the board in writing within 30 days of the date
14 of that change in status.

15 (c) A ~~facility manager~~ *designated representative-3PL* may take
16 charge of, and act as, the ~~facility manager-in-charge~~ *responsible*
17 *manager* of a third-party logistics provider upon application by
18 the third-party logistics provider and approval by the board. A
19 ~~facility manager-in-charge~~ *responsible manager* who ceases to act
20 as the ~~facility manager-in-charge~~ *responsible manager* at that entity
21 shall notify the board in writing within 30 days of the date of that
22 change in status.

23 ~~SEC. 11.~~

24 *SEC. 12.* Section 4105 of the Business and Professions Code
25 is amended to read:

26 4105. (a) All records or other documentation of the acquisition
27 and disposition of dangerous drugs and dangerous devices by any
28 entity licensed by the board shall be retained on the licensed
29 premises in a readily retrievable form.

30 (b) The licensee may remove the original records or
31 documentation from the licensed premises on a temporary basis
32 for license-related purposes. However, a duplicate set of those
33 records or other documentation shall be retained on the licensed
34 premises.

35 (c) The records required by this section shall be retained on the
36 licensed premises for a period of three years from the date of
37 making.

38 (d) (1) Any records that are maintained electronically shall be
39 maintained so that the pharmacist-in-charge, or the pharmacist on
40 duty if the pharmacist-in-charge is not on duty, shall, at all times

during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the ~~facility manager-in-charge~~, *responsible manager*, or the designated representative on duty ~~or the facility manager on duty or the designated representative-3PL on duty~~ if the designated representative-in-charge or ~~facility manager-in-charge~~ *responsible manager* is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

~~SEC. 12.~~

SEC. 13. Section 4107 is added to the Business and Professions Code, to read:

4107. If a manufacturer, wholesaler, third-party logistics provider, or pharmacy has reasonable cause to believe that a dangerous drug or dangerous device in, or having been in, its

1 possession is counterfeit or the subject of a fraudulent transaction,
2 the manufacturer, wholesaler, third-party logistics provider, or
3 pharmacy shall notify the board within 72 hours of obtaining that
4 knowledge. This section shall apply to any dangerous drug or
5 dangerous device that has been sold or distributed in or through
6 this state.

7 ~~SEC. 13.~~

8 *SEC. 14.* Section 4120 of the Business and Professions Code
9 is amended to read:

10 4120. (a) A nonresident pharmacy shall not sell or distribute
11 dangerous drugs or dangerous devices in this state through any
12 person or media other than a wholesaler or third-party logistics
13 provider who has obtained a license pursuant to this chapter or
14 through a selling or distribution outlet that is licensed as a
15 wholesaler or third-party logistics provider pursuant to this chapter
16 without registering as a nonresident pharmacy.

17 (b) Applications for a nonresident pharmacy registration shall
18 be made on a form furnished by the board. The board may require
19 any information as the board deems reasonably necessary to carry
20 out the purposes of this section.

21 (c) The Legislature, by enacting this section, does not intend a
22 license issued to any nonresident pharmacy pursuant to this section
23 to change or affect the tax liability imposed by Chapter 3
24 (commencing with Section 23501) of Part 11 of Division 2 of the
25 Revenue and Taxation Code on any nonresident pharmacy.

26 (d) The Legislature, by enacting this section, does not intend a
27 license issued to any nonresident pharmacy pursuant to this section
28 to serve as any evidence that the nonresident pharmacy is doing
29 business within this state.

30 ~~SEC. 14.~~ ~~Section 4126 of the Business and Professions Code~~
31 ~~is amended to read:~~

32 ~~4126. (a) Notwithstanding any other law, a covered entity may~~
33 ~~contract with a pharmacy to provide pharmacy services to patients~~
34 ~~of the covered entity, as defined in Section 256b of Title 42 of the~~
35 ~~United States Code, including dispensing preferentially priced~~
36 ~~drugs obtained pursuant to Section 256b of Title 42 of the United~~
37 ~~States Code. Contracts between those covered entities and~~
38 ~~pharmacies shall comply with guidelines published by the Health~~
39 ~~Resources and Services Administration and shall be available for~~
40 ~~inspection by board staff during normal business hours.~~

1 ~~(b) Drugs purchased pursuant to Section 256b of Title 42 of the~~
2 ~~United States Code and received by a pharmacy shall be segregated~~
3 ~~from the pharmacy's other drug stock by either physical or~~
4 ~~electronic means. All records of acquisition and disposition of~~
5 ~~these drugs shall be readily retrievable in a form separate from the~~
6 ~~pharmacy's other records.~~

7 ~~(c) Drugs obtained by a pharmacy to be dispensed to patients~~
8 ~~of a covered entity pursuant to Section 256b of Title 42 of the~~
9 ~~United States Code that cannot be distributed because of a change~~
10 ~~in circumstances for the covered entity or the pharmacy shall be~~
11 ~~returned to the distributor from which they were obtained. For the~~
12 ~~purposes of this section, a change in circumstances includes, but~~
13 ~~is not limited to, the termination or expiration of the contract~~
14 ~~between the pharmacy and the covered entity, the closure of a~~
15 ~~pharmacy, disciplinary action against the pharmacy, or closure of~~
16 ~~the covered entity.~~

17 ~~(d) A licensee that participates in a contract to dispense~~
18 ~~preferentially priced drugs pursuant to this section shall not have~~
19 ~~both a pharmacy and a wholesaler license, or both a pharmacy and~~
20 ~~a third-party logistics provider license.~~

21 ~~(e) Neither a covered entity nor a pharmacy shall be required~~
22 ~~to obtain a license as a wholesaler or a third-party logistics provider~~
23 ~~based on acts reasonably necessary to fully participate in the drug~~
24 ~~purchase program established by Section 256b of Title 42 of the~~
25 ~~United States Code.~~

26 SEC. 15. Section 4149 of the Business and Professions Code
27 is amended to read:

28 4149. (a) A nonresident distributor shall not sell or distribute
29 hypodermic needles or syringes in this state without obtaining a
30 license from the board pursuant to Section 4141.

31 (b) Notwithstanding subdivision (a), a license is not required if
32 the nonresident distributor sells or distributes solely through a
33 person who is licensed as a wholesaler or third-party logistics
34 provider pursuant to Section 4160.

35 (c) The Legislature, by enacting this section, does not intend a
36 license issued to any nonresident distributor pursuant to this article
37 to serve as evidence that the entity is doing business within this
38 state.

SEC. 16. The heading of Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

Article 11. Wholesalers, Third-Party Logistics Providers, and
Manufacturers

SEC. 17. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the ~~board~~ board, *except as provided in paragraph (2)*. Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or ~~facility manager~~ *designated representative-3PL* in the case of a third-party logistics provider, shall be present.

(2) *A wholesaler and a third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:*

(A) *The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.*

(B) *Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.*

(C) *Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.*

(D) *The wholesaler has its own designated representative-in-charge responsible for the operations of the*

1 *wholesaler and the third-party logistics provider has its own*
2 *responsible manager responsible for the operations of the*
3 *third-party logistics provider. The same individual shall not*
4 *concurrently serve as the responsible manager and the designated*
5 *representative-in-charge for a wholesaler and a third-party*
6 *logistics provider licensed at the same place of business.*

7 *(E) The third-party logistics provider does not handle the*
8 *prescription drugs or prescription devices owned by a prescriber.*

9 *(F) The third-party logistics provider is not a reverse third-party*
10 *logistics provider.*

11 *(G) The wholesaler is not acting as a reverse distributor.*

12 (d) Every wholesaler shall be supervised or managed by a
13 designated representative-in-charge. The designated
14 representative-in-charge shall be responsible for the wholesaler's
15 compliance with state and federal laws governing ~~wholesalers.~~
16 *wholesalers.* As part of its initial application for a license, and for
17 each renewal, each wholesaler shall, on a form designed by the
18 board, provide identifying information and the California license
19 number for a designated representative or pharmacist proposed to
20 serve as the designated representative-in-charge. The proposed
21 designated representative-in-charge shall be subject to approval
22 by the board. The board shall not issue or renew a wholesaler
23 license without identification of an approved designated
24 representative-in-charge for the ~~wholesaler.~~ *wholesaler. The*
25 *designated representative-in-charge shall maintain an active*
26 *license as a designated representative with the board at all times*
27 *during which he or she is designated as the designated*
28 *representative-in-charge.*

29 (e) Each place of business of a third-party logistics provider
30 shall be supervised and managed by a ~~facility manager-in-charge.~~
31 *responsible manager.* The ~~facility manager-in-charge~~ *responsible*
32 *manager* shall be responsible for the compliance of the place of
33 business with state and federal laws governing third-party logistics
34 providers and with the third-party logistics provider's customer
35 specifications, *except where the customer's specifications conflict*
36 *with state or federal laws.* As part of its initial application for a
37 license, and for each renewal, each third-party logistics provider
38 shall, on a form designated by the board, provide identifying
39 information and the California license number for a ~~facility~~
40 ~~manager~~ *designated representative-3PL* proposed to serve as the

1 ~~facility manager-in-charge~~; *responsible manager*. The proposed
2 ~~facility manager-in-charge~~ *responsible manager* shall be subject
3 to approval by the board. The board shall not issue or renew a
4 third-party logistics provider license without identification of an
5 approved ~~facility manager-in-charge~~ *responsible manager* for the
6 third-party logistics provider. *The responsible manager shall*
7 *maintain an active license as a designated representative-3PL*
8 *with the board at all times during which he or she is designated*
9 *as the responsible manager.*

10 (f) A wholesaler shall notify the board in writing, on a form
11 designed by the board, within 30 days of the date when a
12 designated representative-in-charge ceases to act as the designated
13 representative-in-charge, and shall on the same form propose
14 another designated representative or pharmacist to take over as
15 the designated representative-in-charge. The proposed replacement
16 designated representative-in-charge shall be subject to approval
17 by the board. If disapproved, the wholesaler shall propose another
18 replacement within 15 days of the date of disapproval, and shall
19 continue to name proposed replacements until a designated
20 representative-in-charge is approved by the board.

21 (g) A third-party logistics provider shall notify the board in
22 writing, on a form designed by the board, within 30 days of the
23 date when a ~~facility manager-in-charge~~ *responsible manager* ceases
24 to act as the ~~facility manager-in-charge~~; *responsible manager*, and
25 shall on the same form propose another ~~facility manager~~ *designated*
26 *representative-3PL* to take over as the ~~facility manager-in-charge~~.
27 *responsible manager*. The proposed replacement—~~facility~~
28 ~~manager-in-charge~~ *responsible manager* shall be subject to
29 approval by the board. If disapproved, the third-party logistics
30 provider shall propose another replacement within 15 days of the
31 date of disapproval, and shall continue to name proposed
32 replacements until a ~~facility manager-in-charge~~ *responsible*
33 *manager* is approved by the board.

34 (h) A drug manufacturer premises licensed by the Food and
35 Drug Administration or licensed pursuant to Section 111615 of
36 the Health and Safety Code that only distributes dangerous drugs
37 and dangerous devices of its own manufacture is exempt from this
38 section and Section 4161.

39 (i) The board may issue a temporary license, upon conditions
40 and for periods of time as the board determines to be in the public

1 interest. A temporary license fee shall be required in an amount
2 established by the board as specified in subdivision (f) of Section
3 4400. When needed to protect public safety, a temporary license
4 may be issued for a period not to exceed 180 days, subject to terms
5 and conditions that the board deems necessary. If the board
6 determines that a temporary license was issued by mistake or denies
7 the application for a permanent license, the temporary license shall
8 terminate upon either personal service of the notice of termination
9 upon the licenseholder or service by certified mail, return receipt
10 requested, at the licenseholder's address of record with the board,
11 whichever occurs first. Neither for purposes of retaining a
12 temporary license, nor for purposes of any disciplinary or license
13 denial proceeding before the board, shall the temporary
14 licenseholder be deemed to have a vested property right or interest
15 in the license.

16 SEC. 18. Section 4161 of the Business and Professions Code
17 is amended to read:

18 4161. (a) A person located outside this state that (1) ships,
19 sells, mails, warehouses, distributes, or delivers dangerous drugs
20 or dangerous devices into this state or (2) sells, brokers,
21 warehouses, or distributes dangerous drugs or devices within this
22 state shall be considered a nonresident wholesaler or a nonresident
23 third-party logistics provider.

24 (b) A nonresident wholesaler or nonresident third-party logistics
25 provider shall be licensed by the board prior to shipping, selling,
26 mailing, warehousing, distributing, or delivering dangerous drugs
27 or dangerous devices to a site located in this state or selling,
28 brokering, warehousing, or distributing dangerous drugs or devices
29 within this state.

30 (c) (1) A separate license shall be required for each place of
31 business owned or operated by a nonresident wholesaler or
32 nonresident third-party logistics provider from or through which
33 dangerous drugs or dangerous devices are shipped, sold, mailed,
34 warehoused, distributed, or delivered to a site located in this state
35 or sold, brokered, warehoused, or distributed within this state.
36 Each place of business may only be issued a single license by the
37 board, *except as provided in paragraph (2)*. A license shall be
38 renewed annually and shall not be transferable.

39 (2) *A nonresident wholesaler and a nonresident third-party*
40 *logistics provider under common ownership may be licensed at*

1 *the same place of business provided that all of the following*
2 *requirements are satisfied:*

3 *(A) The wholesaler and the third-party logistics provider each*
4 *separately maintain the records required under Section 4081.*

5 *(B) Dangerous drugs and dangerous devices owned by the*
6 *wholesaler are not commingled with the dangerous drugs and*
7 *dangerous devices handled by the third-party logistics provider.*

8 *(C) Any individual acting as a designated representative for the*
9 *wholesaler is not concurrently acting as a designated*
10 *representative-3PL on behalf of the third-party logistics provider.*
11 *Nothing in this subparagraph shall be construed to prohibit an*
12 *individual from concurrently holding a license to act as a*
13 *designated representative and to act as a designated*
14 *representative-3PL.*

15 *(D) The wholesaler has its own designated*
16 *representative-in-charge responsible for the operations of the*
17 *wholesaler and the third-party logistics provider has its own*
18 *responsible manager responsible for the operations of the*
19 *third-party logistics provider. The same individual shall not*
20 *concurrently serve as the responsible manager and the designated*
21 *representative-in-charge for a wholesaler and a third-party*
22 *logistics provider licensed at the same place of business.*

23 *(E) The third-party logistics provider does not handle the*
24 *prescription drugs or prescription devices owned by a prescriber.*

25 *(F) The third-party logistics provider is not a reverse third-party*
26 *logistics provider.*

27 *(G) The wholesaler is not acting as a reverse distributor.*

28 *(d) The following information shall be reported, in writing, to*
29 *the board at the time of initial application for licensure by a*
30 *nonresident wholesaler or a nonresident third-party logistics*
31 *provider, on renewal of a nonresident wholesaler or nonresident*
32 *third-party logistics provider license, or within 30 days of a change*
33 *in that information:*

34 *(1) Its agent for service of process in this state.*

35 *(2) Its principal corporate officers, as specified by the board, if*
36 *any.*

37 *(3) Its general partners, as specified by the board, if any.*

38 *(4) Its owners if the applicant is not a corporation or partnership.*

1 (e) A report containing the information in subdivision (d) shall
2 be made within 30 days of any change of ownership, office,
3 corporate officer, or partner.

4 (f) A nonresident wholesaler or nonresident third-party logistics
5 provider shall comply with all directions and requests for
6 information from the regulatory or licensing agency of the state
7 in which it is licensed, as well as with all requests for information
8 made by the board.

9 (g) A nonresident wholesaler or nonresident third-party logistics
10 provider shall maintain records of dangerous drugs and dangerous
11 devices sold, traded, transferred, warehoused, or distributed to
12 persons in this state or within this state, so that the records are in
13 a readily retrievable form.

14 (h) A nonresident wholesaler or nonresident third-party logistics
15 provider shall at all times maintain a valid, unexpired license,
16 permit, or registration to conduct the business of the wholesaler
17 or nonresident third-party logistics provider in compliance with
18 the laws of the state in which it is a resident. An application for a
19 nonresident wholesaler or nonresident third-party logistics provider
20 license in this state shall include a license verification from the
21 licensing authority in the applicant's state of residence.

22 (i) ~~(1) The board shall not issue or renew a nonresident~~
23 ~~wholesaler or nonresident third-party logistics provider license~~
24 ~~until the nonresident wholesaler or nonresident third-party logistics~~
25 ~~provider identifies a designated representative-in-charge or facility~~
26 ~~manger-in-charge and notifies the board in writing of the identity~~
27 ~~and license number of the designated representative-in-charge or~~
28 ~~facility manager-in-charge.~~

29 *(2) The board shall not issue or renew a nonresident third-party*
30 *logistics provider license until the nonresident third-party logistics*
31 *provider identifies a responsible manager and notifies the board*
32 *in writing of the identity and license number of the designated*
33 *representative-3PL who will be the responsible manager.*

34 (j) The designated representative-in-charge shall be responsible
35 for the compliance of the nonresident wholesaler with state and
36 federal laws governing wholesalers. ~~The facility manager-in-charge~~
37 *responsible manager* shall be responsible for the compliance of
38 the nonresident third-party logistics provider's place of business
39 with state and federal laws governing third-party logistics
40 providers. A nonresident wholesaler or nonresident third-party

1 logistics provider shall identify and notify the board of a new
2 designated representative-in-charge or ~~facility manager-in-charge~~
3 *responsible manager* within 30 days of the date that the prior
4 designated representative-in-charge or ~~facility manager-in-charge~~
5 *responsible manager* ceases to be the designated
6 representative-in-charge or ~~facility manager-in-charge~~. *responsible*
7 *manager*.

8 (k) The board may issue a temporary license, upon conditions
9 and for periods of time as the board determines to be in the public
10 interest. A temporary license fee shall be five hundred fifty dollars
11 (\$550) or another amount established by the board not to exceed
12 the annual fee for renewal of a license to compound injectable
13 sterile drug products. When needed to protect public safety, a
14 temporary license may be issued for a period not to exceed 180
15 days, subject to terms and conditions that the board deems
16 necessary. If the board determines that a temporary license was
17 issued by mistake or denies the application for a permanent license,
18 the temporary license shall terminate upon either personal service
19 of the notice of termination upon the licenseholder or service by
20 certified mail, return receipt requested, at the licenseholder's
21 address of record with the board, whichever occurs first. Neither
22 for purposes of retaining a temporary license, nor for purposes of
23 any disciplinary or license denial proceeding before the board,
24 shall the temporary licenseholder be deemed to have a vested
25 property right or interest in the license.

26 (l) The registration fee shall be the fee specified in subdivision
27 (f) of Section 4400.

28 *SEC. 19. Section 4161.5 is added to the Business and*
29 *Professions Code, to read:*

30 *4161.5. At such time as federal regulations are promulgated*
31 *to implement Section 584 of the federal Food, Drug, and Cosmetic*
32 *Act (21 U.S.C. Sec. 360eee-3), the board shall immediately identify*
33 *any standard, requirement, or regulation in California law*
34 *governing interstate commerce that is in conflict with the federal*
35 *regulations and act to remove the conflict in the manner permitted*
36 *by law.*

37 ~~SEC. 19.~~

38 *SEC. 20. Section 4162 of the Business and Professions Code*
39 *is amended to read:*

1 4162. (a) (1) An applicant for the issuance or renewal of a
2 wholesaler license, which is not government owned and operated,
3 shall submit a surety bond of one hundred thousand dollars
4 (\$100,000) or other equivalent means of security acceptable to the
5 board payable to the Pharmacy Board Contingent Fund. The
6 purpose of the surety bond is to secure payment of any
7 administrative fine imposed by the board and any cost recovery
8 ordered pursuant to Section 125.3.

9 (2) An applicant for the issuance or renewal of a third-party
10 logistics provider license, which is not government owned and
11 operated, shall submit a surety bond of ninety thousand dollars
12 (\$90,000) or other equivalent means of security acceptable to the
13 board payable to the Pharmacy Board Contingent Fund. The
14 purpose of the surety bond is to secure payment of any
15 administrative fine imposed by the board and any cost recovery
16 ordered pursuant to Section 125.3.

17 (3) For purposes of paragraphs (1) and (2), the board may accept
18 a surety bond less than the amount required under paragraph (1)
19 or (2) if the annual gross receipts of the previous tax year for the
20 wholesaler or third-party logistics provider is ten million dollars
21 (\$10,000,000) or less, in which case the surety bond shall be
22 twenty-five thousand dollars (\$25,000).

23 (4) A person to whom an approved new drug application has
24 been issued by the United States Food and Drug Administration
25 who engages in the wholesale distribution of only the dangerous
26 drug specified in the new drug application, and is licensed or
27 applies for licensure as a wholesaler or third-party logistics
28 provider, shall not be required to post a surety bond as provided
29 in paragraph (1) or (2).

30 (5) For licensees subject to paragraph (3) or (4), the board may
31 require a bond up to one hundred thousand dollars (\$100,000) for
32 any licensee who has been disciplined by any state or federal
33 agency or has been issued an administrative fine pursuant to this
34 chapter.

35 (b) The board may make a claim against the bond if the licensee
36 fails to pay a fine within 30 days after the order imposing the fine,
37 or costs become final.

38 (c) A single surety bond or other equivalent means of security
39 acceptable to the board shall satisfy the requirement of subdivision

1 (a) for all licensed sites under common control as defined in
2 Section 4126.5.

3 ~~SEC. 20.~~

4 *SEC. 21.* Section 4162.5 of the Business and Professions Code
5 is amended to read:

6 4162.5. (a) (1) An applicant for the issuance or renewal of a
7 nonresident wholesaler license shall submit a surety bond of one
8 hundred thousand dollars (\$100,000), or other equivalent means
9 of security acceptable to the board, such as an irrevocable letter
10 of credit, or a deposit in a trust account or financial institution,
11 payable to the Pharmacy Board Contingent Fund. The purpose of
12 the surety bond is to secure payment of any administrative fine
13 imposed by the board and any cost recovery ordered pursuant to
14 Section 125.3.

15 (2) An applicant for the issuance or renewal of a nonresident
16 third-party logistics provider license shall submit a surety bond of
17 ninety thousand dollars (\$90,000), or other equivalent means of
18 security acceptable to the board, such as an irrevocable letter of
19 credit, or a deposit in a trust account or financial institution,
20 payable to the Pharmacy Board Contingent Fund. The purpose of
21 the surety bond is to secure payment of any administrative fine
22 imposed by the board and any cost recovery ordered pursuant to
23 Section 125.3.

24 (3) For purposes of paragraphs (1) and (2), the board may accept
25 a surety bond less than the amount required under paragraph (1)
26 or (2) if the annual gross receipts of the previous tax year for the
27 nonresident wholesaler or the nonresident third-party logistics
28 provider is ten million dollars (\$10,000,000) or less, in which case
29 the surety bond shall be twenty-five thousand dollars (\$25,000).

30 (4) For applicants who satisfy paragraph (3), the board may
31 require a bond up to one hundred thousand dollars (\$100,000) for
32 any nonresident wholesaler or nonresident third-party logistics
33 provider who has been disciplined by any state or federal agency
34 or has been issued an administrative fine pursuant to this chapter.

35 (5) A person to whom an approved new drug application or a
36 biologics license application has been issued by the United States
37 Food and Drug Administration who engages in the wholesale
38 distribution of only the dangerous drug specified in the new drug
39 application or biologics license application, and is licensed or
40 applies for licensure as a nonresident wholesaler or a nonresident

1 third-party logistics provider, shall not be required to post a surety
2 bond as provided in this section.

3 (b) The board may make a claim against the bond if the licensee
4 fails to pay a fine within 30 days of the issuance of the fine or
5 when the costs become final.

6 (c) A single surety bond or other equivalent means of security
7 acceptable to the board shall satisfy the requirement of subdivision
8 (a) for all licensed sites under common control as defined in
9 Section 4126.5.

10 ~~SEC. 21.~~

11 *SEC. 22.* Section 4164 of the Business and Professions Code
12 is amended to read:

13 4164. (a) A wholesaler or third-party logistics provider licensed
14 by the board that distributes controlled substances, dangerous
15 drugs, or dangerous devices within or into this state shall report
16 to the board all distributions of dangerous drugs and controlled
17 substances that are subject to abuse, as determined by the board.

18 (b) Each wholesaler shall develop and maintain a system for
19 tracking individual sales of dangerous drugs at preferential or
20 contract prices to pharmacies that primarily or solely dispense
21 prescription drugs to patients of long-term care facilities. The
22 system shall be capable of identifying purchases of any dangerous
23 drug at preferential or contract prices by customers that vary
24 significantly from prior ordering patterns for the same customer,
25 including by identifying purchases in the preceding 12 calendar
26 months by that customer or similar customers and identifying
27 current purchases that exceed prior purchases by either that
28 customer or similar customers by a factor of 20 percent.

29 (c) Upon written, oral, or electronic request by the board, a
30 wholesaler shall furnish data tracked pursuant to subdivision (b)
31 to the board in written, hardcopy, or electronic form. The board
32 shall specify the dangerous drugs, the customers, or both the
33 dangerous drugs and customers for which data are to be furnished,
34 and the wholesaler shall have 30 calendar days to comply with the
35 request.

36 (d) As used in this section, “preferential or contract prices”
37 means and refers to purchases by contract of dangerous drugs at
38 prices below the market wholesale price for those drugs.

1 ~~SEC. 22.~~

2 ~~SEC. 23.~~ Section 4165 of the Business and Professions Code
3 is amended to read:

4 4165. A wholesaler or third-party logistics provider licensed
5 by the board who sells or transfers any dangerous drug or
6 dangerous device into this state or who receives, by sale or
7 otherwise, any dangerous drug or dangerous device from any
8 person in this state shall, on request, furnish an authorized officer
9 of the law with all records or other documentation of that sale or
10 transfer.

11 ~~SEC. 23.~~

12 ~~SEC. 24.~~ Section 4166 of the Business and Professions Code
13 is amended to read:

14 4166. (a) ~~Any~~A wholesaler that uses the services of ~~any~~ a
15 third-party logistics provider or carrier, including, but not limited
16 to, the United States Postal Service or ~~any~~ a common carrier, shall
17 be liable for the security and integrity of any dangerous drugs or
18 dangerous devices through that provider or carrier until the drugs
19 or devices are delivered to the transferee at its board-licensed
20 premises.

21 (b) *A third-party logistics provider that uses the services of a*
22 *carrier, including, but not limited to, the United States Postal*
23 *Service or a common carrier, shall have in place and comply with*
24 *written policies and procedures that provide for both of the*
25 *following:*

26 (1) *Verification that the third-party logistics provider, or the*
27 *owner of the dangerous drugs or dangerous devices stored at the*
28 *third-party logistics provider, has imposed obligations on the*
29 *carrier that provide for the security and integrity of any dangerous*
30 *drugs or dangerous devices transported by the carrier until the*
31 *drugs or devices are delivered to the transferee at its premises.*

32 (2) *Confirmation, prior to shipping a dangerous drug or*
33 *dangerous device, that the intended recipient is legally authorized*
34 *to receive the dangerous drug or dangerous device.*

35 ~~(b)~~

36 (c) Nothing in this section is intended to affect the liability of
37 a wholesaler, third-party logistics provider, or other distributor for
38 dangerous drugs or dangerous devices after their delivery to the
39 transferee.

~~SEC. 24.~~

SEC. 25. Section 4167 of the Business and Professions Code is amended to read:

4167. A wholesaler or third-party logistics provider shall not obtain, by purchase or otherwise, any dangerous drugs or dangerous devices that it cannot maintain, in a secure manner, at the place of business licensed by the board.

~~SEC. 25.~~

SEC. 26. Section 4168 of the Business and Professions Code is amended to read:

4168. A county or municipality shall not issue a business license for any establishment that requires a wholesaler or third-party logistics provider license unless the establishment possesses a current wholesaler or third-party logistics provider license issued by the board. For purposes of this section, an “establishment” is the licensee’s physical location in California.

~~SEC. 26.~~

SEC. 27. Section 4169 of the Business and Professions Code is amended to read:

4169. (a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

~~SEC. 27.~~

SEC. 28. Section 4201 of the Business and Professions Code is amended to read:

4201. (a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) As used in this section, and subject to subdivision (c), the term “person beneficially interested” means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant

cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~SEC. 28:~~

SEC. 29. Section 4305.5 of the Business and Professions Code is amended to read:

4305.5. (a) A person that is licensed as a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge or ~~facility manager-in-charge~~ *responsible manager*. Failure to notify the

1 board within the 30-day period shall constitute grounds for
2 disciplinary action.

3 (b) A person that is licensed as a wholesaler, third-party logistics
4 provider, or veterinary food-animal drug retailer, that willfully
5 fails to notify the board of the termination of employment of the
6 designated representative-in-charge or ~~facility manager-in-charge~~
7 *responsible manager* at its licensed place of business, and that
8 continues to operate the place of business in the absence of the
9 designated representative-in-charge or ~~facility manager-in-charge~~
10 *responsible manager* for that place of business shall be subject to
11 summary suspension or revocation of its license as a wholesaler,
12 third-party logistics provider, or veterinary food-animal drug
13 retailer at that place of business.

14 (c) A designated representative-in-charge of a wholesaler or
15 veterinary food-animal drug retailer, or a ~~facility manager-in-charge~~
16 *responsible manager* of a third-party logistics provider, who
17 terminates his or her employment at the licensed place of business,
18 shall notify the board within 30 days of the termination of
19 employment. Failure to notify the board within the 30-day period
20 shall constitute grounds for disciplinary action.

21 ~~SEC. 29.~~

22 *SEC. 30.* Section 4312 of the Business and Professions Code
23 is amended to read:

24 4312. (a) The board may cancel the license of a wholesaler,
25 third-party logistics provider, pharmacy, or veterinary food-animal
26 drug retailer if the licensed premises remain closed, as defined in
27 subdivision (e), other than by order of the board. For good cause
28 shown, the board may cancel a license after a shorter period of
29 closure. To cancel a license pursuant to this subdivision, the board
30 shall make a diligent, good faith effort to give notice by personal
31 service on the licensee. If a written objection is not received within
32 10 days after personal service is made or a diligent, good faith
33 effort to give notice by personal service on the licensee has failed,
34 the board may cancel the license without the necessity of a hearing.
35 If the licensee files a written objection, the board shall file an
36 accusation based on the licensee remaining closed. Proceedings
37 shall be conducted in accordance with Chapter 5 (commencing
38 with Section 11500) of Part 1 of Division 3 of Title 2 of the
39 Government Code, and the board shall have all the powers granted
40 in that chapter.

1 (b) If the license of a wholesaler, third-party logistics provider,
2 pharmacy, or veterinary food-animal drug retailer is canceled
3 pursuant to subdivision (a) or revoked pursuant to Article 19
4 (commencing with Section 4300), or a wholesaler, third-party
5 logistics provider, pharmacy, or veterinary food-animal drug
6 retailer notifies the board of its intent to remain closed or to
7 discontinue business, the licensee shall, within 10 days thereafter,
8 arrange for the transfer of all dangerous drugs and controlled
9 substances or dangerous devices to another licensee authorized to
10 possess the dangerous drugs and controlled substances or dangerous
11 devices. The licensee transferring the dangerous drugs and
12 controlled substances or dangerous devices shall immediately
13 confirm in writing to the board that the transfer has taken place.

14 (c) If a wholesaler, third-party logistics provider, pharmacy, or
15 veterinary food-animal drug retailer fails to comply with
16 subdivision (b), the board may seek and obtain an order from the
17 superior court in the county in which the wholesaler, third-party
18 logistics provider, pharmacy, or veterinary food-animal drug
19 retailer is located, authorizing the board to enter the wholesaler,
20 third-party logistics provider, pharmacy, or veterinary food-animal
21 drug retailer and inventory and store, transfer, sell, or arrange for
22 the sale of, all dangerous drugs and controlled substances and
23 dangerous devices found in the wholesaler, third-party logistics
24 provider, pharmacy, or veterinary food-animal drug retailer.

25 (d) If the board sells or arranges for the sale of any dangerous
26 drugs, controlled substances, or dangerous devices pursuant to
27 subdivision (c), the board may retain from the proceeds of the sale
28 an amount equal to the cost to the board of obtaining and enforcing
29 an order issued pursuant to subdivision (c), including the cost of
30 disposing of the dangerous drugs, controlled substances, or
31 dangerous devices. The remaining proceeds, if any, shall be
32 returned to the licensee from whose premises the dangerous drugs
33 or controlled substances or dangerous devices were removed.

34 (1) The licensee shall be notified of his or her right to the
35 remaining proceeds by personal service or by certified mail,
36 postage prepaid.

37 (2) If a statute or regulation requires the licensee to file with
38 the board his or her address, and any change of address, the notice
39 required by this subdivision may be sent by certified mail, postage
40 prepaid, to the latest address on file with the board and service of

1 notice in this manner shall be deemed completed on the 10th day
2 after the mailing.

3 (3) If the licensee is notified as provided in this subdivision,
4 and the licensee fails to contact the board for the remaining
5 proceeds within 30 calendar days after personal service has been
6 made or service by certified mail, postage prepaid, is deemed
7 completed, the remaining proceeds shall be deposited by the board
8 into the Pharmacy Board Contingent Fund. These deposits shall
9 be deemed to have been received pursuant to Chapter 7
10 (commencing with Section 1500) of Title 10 of Part 3 of the Code
11 of Civil Procedure and shall be subject to claim or other disposition
12 as provided in that chapter.

13 (e) For the purposes of this section, “closed” means not engaged
14 in the ordinary activity for which a license has been issued for at
15 least one day each calendar week during any 120-day period.

16 (f) Nothing in this section shall be construed as requiring a
17 pharmacy to be open seven days a week.

18 ~~SEC. 30.~~

19 *SEC. 31.* Section 4331 of the Business and Professions Code
20 is amended to read:

21 4331. (a) A person who is ~~neither a pharmacist nor~~ *not a*
22 *pharmacist, a designated representative-in-charge, or a designated*
23 *representative and who takes charge of a wholesaler or veterinary*
24 *food-animal drug retailer or who dispenses a prescription or*
25 *furnishes dangerous devices, except as otherwise provided in this*
26 *chapter, is guilty of a misdemeanor.*

27 (b) A person who is not a ~~facility manager~~ *responsible manager*
28 *or a designated representative-3PL* who takes charge of a
29 third-party logistics provider or coordinates the warehousing or
30 distribution of dangerous drugs or dangerous devices within a
31 third-party logistics provider, except as otherwise provided in this
32 chapter, is guilty of a misdemeanor.

33 (c) A person licensed as a veterinary food-animal drug retailer
34 that fails to place in charge of that veterinary food-animal drug
35 retailer a pharmacist or designated representative, or any person
36 who, by himself or herself, or by any other person, permits the
37 dispensing of prescriptions, except by a pharmacist or designated
38 representative, or as otherwise provided in this chapter, is guilty
39 of a misdemeanor.

(d) A person licensed as a wholesaler that fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(e) A person licensed as a third-party logistics provider that fails to place in charge of a licensed place of business of the third-party logistics provider a ~~facility manager~~, *responsible manager*, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a facility manager, or as otherwise provided in this chapter, is guilty of a misdemeanor.

~~SEC. 31.~~

SEC. 32. Section 4400 of the Business and Professions Code, as added by Section 9 of Chapter 565 of the Statutes of 2013, is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a ~~facility manager~~ *designated representative-3PL* pursuant to Section 4053.1, shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

(2) The fee for the annual renewal of a license as a designated representative or ~~facility manager~~ *designated representative-3PL* shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after

1 licensure of the first 20 locations shall be three hundred dollars
2 (\$300) and may be decreased to no less than two hundred
3 twenty-five dollars (\$225). A temporary license fee shall be seven
4 hundred fifteen dollars (\$715) and may be decreased to no less
5 than five hundred fifty dollars (\$550).

6 (3) The annual renewal fee for a nonresident wholesaler license
7 or third-party logistics provider license issued pursuant to Section
8 4161 shall be seven hundred eighty dollars (\$780) and may be
9 decreased to no less than six hundred dollars (\$600).

10 (k) The fee for evaluation of continuing education courses for
11 accreditation shall be set by the board at an amount not to exceed
12 forty dollars (\$40) per course hour.

13 (l) The fee for an intern pharmacist license shall be ninety dollars
14 (\$90) and may be increased to one hundred fifteen dollars (\$115).
15 The fee for transfer of intern hours or verification of licensure to
16 another state shall be twenty-five dollars (\$25) and may be
17 increased to thirty dollars (\$30).

18 (m) The board may waive or refund the additional fee for the
19 issuance of a license where the license is issued less than 45 days
20 before the next regular renewal date.

21 (n) The fee for the reissuance of any license, or renewal thereof,
22 that has been lost or destroyed or reissued due to a name change
23 shall be thirty-five dollars (\$35) and may be increased to forty-five
24 dollars (\$45).

25 (o) The fee for the reissuance of any license, or renewal thereof,
26 that must be reissued because of a change in the information, shall
27 be one hundred dollars (\$100) and may be increased to one hundred
28 thirty dollars (\$130).

29 (p) It is the intent of the Legislature that, in setting fees pursuant
30 to this section, the board shall seek to maintain a reserve in the
31 Pharmacy Board Contingent Fund equal to approximately one
32 year's operating expenditures.

33 (q) The fee for any applicant for a nongovernmental clinic
34 license shall be four hundred dollars (\$400) and may be increased
35 to five hundred twenty dollars (\$520) for each license. The annual
36 fee for renewal of the license shall be two hundred fifty dollars
37 (\$250) and may be increased to three hundred twenty-five dollars
38 (\$325) for each license.

39 (r) The fee for the issuance of a pharmacy technician license
40 shall be eighty dollars (\$80) and may be increased to one hundred

1 five dollars (\$105). The fee for renewal of a pharmacy technician
2 license shall be one hundred dollars (\$100) and may be increased
3 to one hundred thirty dollars (\$130).

4 (s) The fee for a veterinary food-animal drug retailer license
5 shall be four hundred five dollars (\$405) and may be increased to
6 four hundred twenty-five dollars (\$425). The annual renewal fee
7 for a veterinary food-animal drug retailer license shall be two
8 hundred fifty dollars (\$250) and may be increased to three hundred
9 twenty-five dollars (\$325).

10 (t) The fee for issuance of a retired license pursuant to Section
11 4200.5 shall be thirty-five dollars (\$35) and may be increased to
12 forty-five dollars (\$45).

13 (u) The fee for issuance or renewal of a nongovernmental sterile
14 compounding pharmacy license shall be six hundred dollars (\$600)
15 and may be increased to seven hundred eighty dollars (\$780). The
16 fee for a temporary license shall be five hundred fifty dollars (\$550)
17 and may be increased to seven hundred fifteen dollars (\$715).

18 (v) The fee for the issuance or renewal of a nonresident sterile
19 compounding pharmacy license shall be seven hundred eighty
20 dollars (\$780). In addition to paying that application fee, the
21 nonresident sterile compounding pharmacy shall deposit, when
22 submitting the application, a reasonable amount, as determined by
23 the board, necessary to cover the board's estimated cost of
24 performing the inspection required by Section 4127.2. If the
25 required deposit is not submitted with the application, the
26 application shall be deemed to be incomplete. If the actual cost of
27 the inspection exceeds the amount deposited, the board shall
28 provide to the applicant a written invoice for the remaining amount
29 and shall not take action on the application until the full amount
30 has been paid to the board. If the amount deposited exceeds the
31 amount of actual and necessary costs incurred, the board shall
32 remit the difference to the applicant.

33 (w) This section shall become operative on July 1, 2014.

34 ~~SEC. 32.~~

35 *SEC. 33.* No reimbursement is required by this act pursuant
36 to Section 6 of Article XIII B of the California Constitution because
37 the only costs that may be incurred by a local agency or school
38 district will be incurred because this act creates a new crime or
39 infraction, eliminates a crime or infraction, or changes the penalty
40 for a crime or infraction, within the meaning of Section 17556 of

- 1 the Government Code, or changes the definition of a crime within
- 2 the meaning of Section 6 of Article XIII B of the California
- 3 Constitution.

O